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# EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

**No.** **CE 501520**

Issued To: **Corporation STERIS Canada**
**(also Operating as STERIS Canada ULC)**
**490 Boulevard Armand-Paris**
**Québec (Québec)**
**G1C 8A3**
**Canada**

In respect of:

**The design and manufacture of washer-disinfectors and sterile processing equipment for healthcare facilities.**

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Albert Roossien, Regulatory Lead

First Issued: **2005-11-02** Date: **2019-01-03** Expiry Date: **2023-07-19**

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Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
A member of BSI Group of Companies.

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# EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

## List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

| | |
|---|---|
| Certificate No: | **CE 501520** |
| Date: | **2019-01-03** |
| Issued To: | **Corporation STERIS Canada**<br>**(also Operating as STERIS Canada ULC)**<br>**490 Boulevard Armand-Paris**<br>**Québec (Québec)**<br>**G1C 8A3**<br>**Canada** |

| **Subcontractor:** | **Service(s) supplied** |
|---|---|
| STERIS Corporation<br>5960 Heisley Road<br>Mentor<br>Ohio<br>44060<br>USA | **Design** |
| STERIS Ireland Limited<br>IDA Business & Technology Park<br>Tullamore<br>Co. Offaly<br>R35 X865<br>Ireland | **EU Representative** |

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# EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 501520**

Date: **2019-01-03**

Issued To: **Corporation STERIS Canada**
**(also Operating as STERIS Canada ULC)**
**490 Boulevard Armand-Paris**
**Québec (Québec)**
**G1C 8A3**
**Canada**

| Date | Reference Number | Action |
|---|---|---|
| 02 November 2005 | | First Issue. Transfer from TUV, certificate number G1 03 09 24353 002. |
| 24 April 2007 | | Re-issue due to change of town in company address. Amendment of TUV Certificate number on history page. |
| 10 September 2008 | 7161614 | Certificate Renewal. |
| 20 July 2013 | 8000916 | Certificate Renewal.<br>Addition of STERIS Ltd. as the EU Representative. |
| 10 April 2015 | 8286662 | Extension to scope to include sterile processing equipment, removal of accessories from scope and addition of ENDO-TECHNIK Wolfgang Griesat GmbH as a significant subcontractor for design and manufacture. |
| 23 January 2016 | 8455721 | Certificate reissue due to legal manufacturer name change from Steris Canada Corporation to Corporation STERIS Canada, 490 Boulevard Armand-Paris, Québec (Québec), CANADA G1C 8A3. |

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# EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 501520**

Date: **2019-01-03**

Issued To: **Corporation STERIS Canada**
**(also Operating as STERIS Canada ULC)**
**490 Boulevard Armand-Paris**
**Québec (Québec)**
**G1C 8A3**
**Canada**

| Date | Reference Number | Action |
|---|---|---|
| 03 July 2018 | 8897989 | Certificate Renewal.<br>Change EU Representative to Steris Ireland Limited.<br>Remove significant sub-contractor ENDO-TECHNIK Wolfgang Griesat GmbH.<br>Add significant sub-contractor Steris Corporation, 5960 Heisley Road, Mentor, OH for design.<br>Amend main address details to include "also operating as STERIS Canada ULC". |
| Current | 8935067 | Traceable to NB 0086. |





Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
A member of BSI Group of Companies.

STERIS Canada ULC
490 boulevard Armand-Paris
Québec (Québec)
Québec
G1C 8A3
Canada

20 Sept 2023

**Notified Body Confirmation Letter**

**Reference: EU2023-607/693022**

To whom it may concern,

**Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices**

This letter confirms that, **BSI Group The Netherlands B.V.**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **2797** on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

STERIS Canada ULC
490 boulevard Armand-Paris
Québec (Québec)
Québec
G1C 8A3
Canada

SRN Number: CA-MF-000017563

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR

application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of BSI Group The Netherlands B.V.,

Alan Till

Digitally signed by Alan Till
Date: 2023.09.20 22:21:55 +01'00'

Alan Till

BSI Scheme Manager

**Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:**

| Device name or Basic UDI-DI (under MDR application) | MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage) | If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device | MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification |
|---|---|---|---|
| Vision Multi-Chamber washer/disinfector | Class IIa | Not Applicable | EC certificate # 501520<br>Expiry date 2023-07-19<br>NB # 2797 |
| Vision 1321 Cart and Utensils Washer/Disinfector<br>Vision 1330L Cart and Utensils Washer/Disinfector<br>Vision 1327 Cart Washer/Disinfector | Class IIa | Not Applicable | EC certificate # 501520<br>Expiry date 2023-07-19<br>NB # 2797 |
| AMSCO 2532 Single-Chamber Washer/Disinfector | Class IIa | Not Applicable | EC certificate # 501520<br>Expiry date 2023-07-19<br>NB # 2797 |
| AMSCO 3052 Single-Chamber Washer/Disinfector | Class IIa | Not Applicable | EC certificate # 501520<br>Expiry date 2023-07-19<br>NB # 2797 |
| AMSCO 5052 Single-Chamber Washer/Disinfector | Class IIa | Not Applicable | EC certificate # 501520<br>Expiry date 2023-07-19<br>NB # 2797 |
| AMSCO 7052HP / 7053HP Single-Chamber Washer/Disinfector | Class IIa | Not Applicable | EC certificate # 501520<br>Expiry date 2023-07-19<br>NB # 2797 |
| Reliance EPS Endoscope Processing System (PTX) | Class IIb – non implantable | Not Applicable | EC certificate # 501520<br>Expiry date 2023-07-19<br>NB # 2797 |

**Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:**

| Device name or Basic UDI-DI (under MDR application) | MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage) | If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device | MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification |
|---|---|---|---|
| N/A | N/A | N/A | N/A |

## Confirmation Letter Revision History

| Date | Action |
|---|---|
| 2023/09/20 | Initial issue |

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# Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

| | |
|---|---|
| Manufacturer name | Corporation STERIS Canada<br>(also operating as STERIS Canada ULC) |
| Manufacturer address and contact details | 490 Boulevard Armand-Paris, Québec (Québec), G1C 8A3, Canada |
| Single Registration Number (SRN) (if available) | CA-MF-000017563 |

| | |
|---|---|
| Authorised Representative name (if applicable) | STERIS Ireland Limited |
| Authorised Representative address and contact details | IDA Business & Technology Park, Tullamore, Co. Offaly, R35 X865, Ireland |
| Single Registration Number (SRN) (if available) | IE-AR-000010065 |

| | |
|---|---|
| Notified body name (if applicable) | □ See attached schedule |
| Notified body number (if applicable) | □ See attached schedule |
| Directive Certificate number(s) to which this confirmation is made (if applicable) | □ See attached schedule |
| Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable) | □ See attached schedule |
| End date of extended validity/transition period | □ See attached schedule |

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*[2]
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

  *Choose applicable statements:*

  ☐ Expired *before* 20 March 2023:

  ☐ Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or

  ☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or

  ☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

  *Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:*

  ☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

  ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

[2] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body



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☒ Expired/expires *after* 20 March 2023:

*Choose one applicable statement:*

☒ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Upclassified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

*Choose one applicable statement:*

☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitutes and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Quality Management System (QMS)**

*Choose one applicable statement:*

☐ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.

☒ A QMS in accordance with Article 10(9) MDR is in place.

☐ A notified body has issued the attached certificate for the MDR-compliant QMS.

➢ **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

**Signed for and on behalf of the manufacturer:**

Full Company Name: Corporation STERIS Canada

Date: Aug 1, 2023

Signature:

Print Name: James Shearn

Title: Director, Regulatory Affairs & Quality Compliance



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**Schedule of Devices**

The above Manufacturer's Declaration is valid for the following devices:

| **Identification of the device(s)**[3] (e.g., device name, family/group name device model or catalogue number) | **Directive Certificate number(s) to which this confirmation is made** (if applicable) | **Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable) | **Notified Body name and number that issued the Directive Certificate** (if applicable) | **End date of extended validity / transition period** | **Substitute Device(s)** (if applicable) |
|---|---|---|---|---|---|
| Vision 1321 Cart and Utensils Washer/Disinfector<br>Vision 1327 Cart and Utensils Washer/Disinfector<br>Vision 1330L Cart and Utensils Washer/Disinfector | CE 501520 | 2023-07-19 | BSI – British Standards Institution - 2797 | 2028-12-31 | n/a |
| Vision Multi-Chamber washer/disinfector | CE 501520 | 2023-07-19 | BSI – British Standards Institution - 2797 | 2028-12-31 | n/a |
| Vision Single-Chamber washer/disinfector | CE 501520 | 2023-07-19 | BSI – British Standards Institution - 2797 | 2028-12-31 | n/a |
| Vision Single-Chamber Large washer/disinfector | CE 501520 | 2023-07-19 | BSI – British Standards Institution - 2797 | 2028-12-31 | n/a |
| AMSCO 2532 Single-Chamber Washer/Disinfector | CE 501520 | 2023-07-19 | BSI – British Standards Institution - 2797 | 2028-12-31 | n/a |
| AMSCO 3052 Single-Chamber Washer/Disinfector | CE 501520 | 2023-07-19 | BSI – British Standards Institution - 2797 | 2028-12-31* | n/a |
| AMSCO 5052 Single-Chamber Washer/Disinfector | CE 501520 | 2023-07-19 | BSI – British Standards Institution - 2797 | 2028-12-31 | n/a |
| Reliance EPS Endoscope Processing System (PTX) | CE 501520 | 2023-07-19 | BSI – British Standards Institution - 2797 | 2028-12-31 | n/a |
| Reliance 200 Endoscope Processing System | CE 501520 | 2023-07-19 | BSI – British Standards Institution - 2797 | 2028-12-31 | n/a |

*Subject to submission of application to the Notified Body prior to the 26th May 2024.

[3] for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)



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